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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/834,095	04/12/2001	Yoshihiro Kawaoka	800.026US1	5332

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MCKELVEY, TERRY ALAN

ART UNIT	PAPER NUMBER
1636	8

DATE MAILED: 07/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/834,095	KAWAOKA, YOSHIHIRO
	<b>Examiner</b>	<b>Art Unit</b>
	Terry McElvey	1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

**A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.**

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on \_\_\_\_ .
- 2a) This action is FINAL.                  2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) 1-26 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_ is: a) approved b) disapproved by the Examiner.  
 If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_ .
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ .

- 4) Interview Summary (PTO-413) Paper No(s).  
 5) Notice of Informal Patent Application (PTO-152)  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9 and 25-26, drawn to recombinant influenza virus comprising mutant ion channel protein and host cell, classified in class 435, subclasses 235.1 and 325.
- II. Claims 10 and 18-21, drawn to vaccine and method of immunizing, classified in class 424, subclass 209.1.
- III. Claims 11-13, drawn to method of preparing influenza virus, classified in class 435, subclass 236.
- IV. Claims 14-17, drawn to vector encoding a chimeric protein, classified in class 435, subclass 320.1.
- V. Claims 22-24, drawn to composition comprising plurality of vectors, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

The virus of Group I and the vaccine and method of immunizing of Group II are distinct products (which have distinct properties) and use of the distinct product capable of

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separate use. A vaccine differs from a virus in that vaccines are compositions which contain multiple ingredients such as a virus, sometimes an adjuvant, and a pharmaceutically acceptable carrier, which together have the property of stimulating the immune system such that protective immunity results. The virus in the vaccine composition is not necessarily live, intact or capable of self-replication. A virus is a genetic package comprising nucleic acid and protein which has the property of being capable of self-replication (and does not necessarily have the properties which distinguish a vaccine such as being in a pharmaceutically acceptable carrier and being capable of stimulating the immune system to provide protective immunity). In the instant case, the virus of Group I can be used in a materially different process from that of the vaccine of Group II, eg. to express heterologous gene products.

Inventions of Group III and Group I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the product as claimed can be made by a materially different process, by chemical mutagenesis.

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The virus of Group I, the vector of Group IV, and the composition comprising a plurality of vectors of Group V are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of one group is not needed to make the products of the other groups. Therefore, the inventions of the three groups are capable of supporting separate patents.

Inventions of Group II and Group III are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The vaccine of Group II is not used in the methods of Group III. The operation, function and effects of the vaccine of Group I (i.e. for eliciting protective immunity) are completely different and distinct from the operation, function and effects of the method of Group III which is a method for preparing an influenza virus. Therefore, the inventions of these different, distinct groups are capable of supporting separate patents.

The vaccine of Group II, the vector of Group IV, and the composition comprising a plurality of vectors of Group V are chemically, biologically, and functionally distinct from each other and thus one does not render the other obvious. The product of one group is not needed to make the products of the

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other groups. Therefore, the inventions of the three groups are capable of supporting separate patents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for Group IV is not required for Group V, with regard to the nonpatent literature search because the two different vector/vector composition are comprised of vectors that have different structural elements that must be separately searched for, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

This application contains claims directed to the following patentably distinct species of the claimed invention: influenza virus, etc drawn to comprising a mutant ion channel protein, each different mutant ion channel protein is a different species (all five groups), and specific set of four or more vectors (Groups III and V). The specific mutant ion channel protein that the invention is drawn to must be elected, and, for Groups

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III and V, the specific set of four or more vectors must also be elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, 9-12, and 14-26 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or

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identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### **Conclusion**

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

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Any inquiry concerning missing attachments or other minor formalities of this communication should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3291.

Any inquiry concerning rejections or other major issues in this communication or earlier communications from the examiner should be directed to Terry A. McKelvey whose telephone number is (703) 305-7213. The examiner can normally be reached on Monday through Friday, except for Wednesdays, from about 7:30 AM to about 6:00 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to his office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Terry A. McKelvey, Ph.D.  
Primary Examiner  
Art Unit 1636

June 29, 2002